: 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Schedule of Visits and Use of Telemedicine for Routine Antenatal Care

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Schedule of Visits and Use of Telemedicine for Routine Antenatal Care,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

5600 Fishers Lane

Mail Stop 06E53A

Rockville, MD 20857

Shipping Address (FedEx, UPS, etc.):

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5600 Fishers Lane

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FOR FURTHER INFORMATION CONTACT:

Jenae Benns, Telephone: 301-427-1496 or Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Schedule of Visits and Use of Telemedicine for Routine Antenatal Care*. AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Schedule of Visits and Use of Telemedicine for Routine Antenatal Care*, including those that describe adverse events.

The entire research protocol is available online at:

https://effectivehealthcare.ahrq.gov/products/schedule-visits-antenatal-care/protocol

This is to notify the public that the EPC Program would find the following information on *Schedule of Visits and Use of Telemedicine for Routine Antenatal Care* helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number*.
    - *For completed studies that do not have results on ClinicalTrials.gov*, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this indication*. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in

the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: https://www.effectivehealthcare.ahrq.gov/email-updates.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQs)

KQ 1: What are the benefits and harms of different antenatal care schedules that vary by number or timing of visits for pregnancies requiring routine care and monitoring?

KQ 2: What are the benefits and harms of telemedicine for providing routine antenatal care during pregnancy?

KQ 3: What are patient, partner/family, and provider perspectives, preferences, and experiences related to antenatal care visit schedules and use of telemedicine for routine antenatal care?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

Category	Definition
Population	**KQ 1 & 2:** • Pregnant individuals receiving routine / standard / basic / traditional antenatal care • Allow studies of pregnant individuals at increased risk of poor outcomes (e.g., with gestational diabetes, gestational hypertension, fetal growth restriction, those receiving part of their antenatal care by maternal-fetal medicine [MFM] or other specialists), as long as the study pertains to their routine antenatal care (i.e., not specifically to their enhanced care for their high-risk condition) **KQ3:** • Pregnant individuals • Postpartum individuals • Individuals considering or planning pregnancy • Partners/family • Providers of antenatal care (any profession or licensure) Allow studies that include high-risk patients, as long as the interventions being assessed pertain to routine care
Interventions	**KQ1** • Defined routine antenatal care schedules with focus on: ▪ Total number of planned visits ▪ Overall schedule (timing, frequency, cadence) ▪ Number of planned in-person visits • Providers of routine antenatal visits include :Obstetricians/gynecologists, nurse practitioners, nurse midwives, nurses, physician assistants, family medicine clinicians • Include interventions designed to evaluate different types of providers (e.g., a nurse instead of a doctor) if there is a concomitant comparison of different schedule of planned visits • Include interventions designed to evaluate group visits if the group visits replace individual visits and there is a concomitant comparison of different schedule of planned visits • Include interventions designed to evaluate home visits if the home visits replace in-clinic visits and there is a concomitant comparison of different schedule of planned visits **KQ2:** • Antenatal care programs using telemedicine, including remote synchronous (real-time visits such as video calls) and asynchronous interactions (e.g., portal email discussions) Allow inclusion of devices designed to transmit information *only if u*se of the devices are part of telemedicine interactions between patients and providers **KQ3:** • Routine antenatal care, specific to interventions covered in KQ 1 and 2
Comparators	**KQ1:** • Standard, routine, or alternative antenatal care schedule (as defined by the study) **KQ2:** • All in-person care, alternative telemedicine/remote care • No (explicit) comparator **KQ3:** • Not applicable
Outcomes (prioritized outcomes have an asterisk)	**KQ1 & KQ2:** • Pregnancy complications: ▪ Maternal mortality ▪ Antenatal pregnancy complications ▪ Delivery-related complications • Other maternal health outcomes: ▪ Delivery outcomes ▪ Inappropriate weight gain ▪ Postpartum contraception—must be adjusted to account for patient preferences

	• Maternal psychosocial, preferences, and related outcomes: ▪ Quality of life measures* ▪ Psychosocial measures ▪ Mental health measures or diagnosis (e.g., anxiety, depression)* ▪ Patient satisfaction with antenatal care* ▪ Patient preferences ▪ Resources • Fetal/neonatal/infant outcomes: ▪ Delivery timing ▪ Mortality ▪ Perinatal morbidity (e.g., birth trauma) ▪ Small for gestational age (e.g., birth weight <10% for similar age neonates)*, low birth weight (e.g., <2.5 kg [5 lb, 8 oz])* ▪ Abnormal Apgar score (threshold, e.g. <7)* ▪ Breastfeeding*—must be adjusted to account for patient preferences ▪ Need for social services • Care utilization: ▪ Attendance at planned antenatal visits (adherence/compliance) ▪ Completion of ACOG recommended services* ▪ Number of unplanned visits* ▪ Number of referrals to other providers ▪ Unplanned hospital admissions ▪ Emergency room/triage visits ▪ Neonatal intensive care unit [NICU] admissions* / length of stay ▪ Number of unplanned contacts (e.g., portal/phone messages) • Provider outcomes: ▪ Provider satisfaction with antenatal care • Harms: ▪ Overdiagnosis (“unnecessary” negative workups or misdiagnoses) ▪ Delayed diagnoses (e.g., gestational diabetes)* ▪ Harms to marginalized groups / equity outcomes **KQ3:** • Perspectives and preferences related to interventions covered by KQ 1 and KQ 2 • Barriers and facilitators related to interventions covered by KQ 1 and KQ 2

Study Design	**KQ1 & KQ2:**
	• Comparative studies (comparisons of different interventions), including parallel design, pre-post studies, and other comparisons
	  ▪ Randomized or observational (nonrandomized)
	  ▪ Prospective or retrospective
	• Surveys that compare interventions (specifically for patient preferences and satisfaction)
	• Registry (e.g., PRAMS [Pregnancy Risk Assessment Monitoring System], National family study) and other retrospective data sources may be eligible, but only if the comparison is between different numbers of planned or scheduled visits (KQ1) or if there is a specific evaluation of telemedicine 9KQ2)
	• Single group studies (no direct comparison of interventions)
	  ▪ Preference and satisfaction outcomes only
	• N ≥10 per intervention group
	• (Existing systematic reviews and guidelines will be used as sources of otherwise missed eligible studies)
	KQ3:
	• Qualitative studies
	• Interviews
	• Focus groups
	• Ethnographic studies
	• Surveys with open-ended questions amenable to qualitative analysis

Timing	**KQ1 & KQ2:** • Interventions: During antenatal period (excluding labor and delivery) • Followup/Outcomes: Any (antenatal, peripartum, postpartum, or later) **KQ3**: • Any (as long as interventions of interest occurred during antenatal period)
Setting	**All KQs:** • High income countries based on World Bank classifications • Outpatient care

Dated: August 18, 2021.

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Associate Director.

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